

REMARKS

Reconsideration and withdrawal of the rejections of the pending claims and prompt issuance of a Notice of Allowance are respectfully requested in view of the amendments and remarks herewith and the matters discussed during the personal interview on 15 December 2009, for which the Examiner is thanked for the courtesies extended.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 132-152 are pending in this application. Claim 132 is the claim discussed during the interview as distinguishing over Quelle, and claims 133-152 are based on the claims previously pending. Claims 132-152 are provided as a new claim set for the convenience of the Examiner. And all of claims 132-152 have been provided without prejudice, without admission, without surrender of subject matter and without any intention of creating any estoppel as to equivalents, and to round out the subject matter claimed.

The Examiner is thanked for withdrawing the previous objections and rejections, and acknowledging the IDS. The present claims address the matters which the Office Action asserted to be informalities, and hence overcome the objections. Reconsideration and withdrawal of the objections are respectfully requested.

The amendments to the specification were also discussed during the interview. They are made to correct obvious typographical errors, and are also fairly based on US application Serial No. 09/169,178, now US Patent No. 6,103,526, which is incorporated by reference into the present application.

No new matter is added.

It is respectfully submitted that the claims, herewith and as originally presented, are patentably distinct over the art, and that those claims are and were in full compliance with the requirements of 35 U.S.C. § 112. The remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, the amendments and remarks herewith are made simply to round out the scope of protection to which Applicant is entitled.

II. THE ART REJECTIONS ARE OVERCOME

Claims 96-97, 99-116 and claim 130 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Quelle *et al.* (“Quelle”) with evidence provided by Dorland’s Illustrated Medical Dictionary. The rejections are respectfully traversed and will be addressed collectively.

Varying conditions for making a biological results in different products.

As discussed during the interview, the claims are product-by-process claims, and the process by which a biological product is made defines the biological product. That is, with regard to a making a biological product, the literature is replete with examples of different biological products resulting from varying process conditions, i.e., when process conditions for making a biological product are changed, the biological product itself is changed.

Quelle illustrates that varying the medium obtains different products.

Quelle amply illustrated that when the process conditions for making a biological are changed—and particularly when the medium is changed—the biological product is changed, as discussed during the interview.

As discussed during the interview, Quelle employed 10% FCS in producing EPO in a baculovirus expression system (page 652, right hand column). Quelle also used 4% FCS in producing EPO in a *Sf* cell baculovirus expression system (pages 653, and 654).

The 10% FCS *Sf* cell baculovirus expression system yielded a 26Kd MW EPO, whereas the 4% FCS *Sf* cell baculovirus expression system yielded 26, 24 and 22 Kd MW EPOs. The difference between the EPOs was said to be due to “differential glycosylation” (page 654). Indeed, the 22 and 24 Kd MW EPOs “produced by *S. fugiperda* cells cultured in low serum correspond to alternatively glycosylated products” (page 656).

With the greater than 4% FCS *Sf* cell baculovirus expression system, a “singular form” of EPO having a 26 kD MW was obtained by Quelle, whereas multiple forms of varying molecular weights (26, 24, 22 Kd MWs) were obtained with 4% FCS *Sf* cell baculovirus expression system (page 653).

Quelle thus shows that in a process for making a biological, if a condition of the process is changed—and particularly when the medium is changed—the biological product is changed.

And thus, Quelle demonstrates that the process recitations of the instant claims patentably distinguish the claimed subject matter from Quelle.

Quelle does not teach the “serum-free” recitation of the instant claims.

Against this background, as also discussed during the interview, the claims recite that the EPO of the invention is produced by a baculovirus expression system *in serum-free cultured insect cells*.¹ Quelle fails to teach or suggest—and as discussed herein teaches away from—using serum-free conditions in producing EPO in a baculovirus expression system.

Since Quelle amply demonstrates that varying the culture conditions, and particularly the serum in the medium, varies the product obtained, the product of the instant claims—from serum-free conditions—is different from that of Quelle and not anticipated by Quelle.

Indeed, not only did the different serum conditions of Quelle obtain varying products (e.g., 26 Kd MW EPO vs 22, 24 and 26 Kd EPOs), whereas Quelle asserts that the 24 and 26 Kd MW EPOs that Quelle obtained have approximately the same *in vitro* biological activity, because the 22 Kd EPO “was found to bind poorly, if at all, to concanavalin A agarose” and “its low abundance,” Quelle did not even estimate any biological activity for this product (page 655). But, Quelle affirmatively asserts that the 22 Kd EPO, “possesses a third distinct oligosaccharide constitution” (page 655), and thereby confirms that lowering the amount of serum obtained a plurality of *different* products. And, Quelle confirms that varying the culture conditions, and particularly the serum in the medium, varies the product obtained.

Hence, Quelle does not teach the instantly claimed invention and does not anticipate the instantly claimed invention because Quelle does not teach any EPO from serum-free conditions as recited in the instant claims. The process recitations for making the EPO of the instant claims thus patentably distinguishes the presently claimed subject matter from Quelle.

¹ Previous claims 113 and 114 recited that “the medium is serum free”. It is respectfully submitted that the allowability of previous claims 113 and 114 over Quelle was not appreciated by the USPTO in issuing the June 22, 2009 Office Action. Furthermore, in view of previous claims 113 and 114, new claim 132 actually presents no new issues, and any further action on the merits other than a Notice of Allowance cannot be a final office action because the “serum-free” recitation had previously been before the Examiner when the June 22, 2009 Office Action was issued. That is, any further action on the merits in this case, other than a Notice of Allowance, in view of the previous claims—including previous claims 113 and 114—must be non-final, because any new rejection has not been necessitated by this paper.

Quelle does not teach the “in vivo activity” recitation of the instant claims.

As to the EPOs that Quelle did assay for biological activity, Quelle affirmatively concluded that they “lack ... *in vivo* activity” due to “[t]he absence of sialic acid in insect-derived saccharide structures” (page 656).

In contrast, the EPO of the instant claims, “has *in vivo* activity, including stimulating erythropoiesis.”² Quelle clearly does not anticipate the instantly claimed invention.

Quelle especially does not teach the “serum free” and “*in vivo* activity” recitations of the instant claims. The product recitations of the EPO of the instant claims thus patentably distinguishes the presently claimed subject matter from Quelle.

Quelle does not suggest—and in fact teaches away from—the instant invention.

Not only does Quelle directly teach that EPOs from an *Sf* cell baculovirus expression system “lack ... *in vivo* activity” and hence teach away from the *in vivo* activity recitation of the instant claims, that Quelle obtained a plurality of products, including at least one form of EPO that could not be assayed for biological activity, from ***lowering*** the amount of serum used, Quelle thus teaches away from the serum-free recitation of the instant claims. From Quelle’s teachings involving obtaining a single product when at high serum is used and obtaining a plurality of products when a low serum amount is used, it would be counter-intuitive to use serum-free conditions to make EPO in a baculovirus expression system.

Accordingly, Quelle does not teach or suggest the instantly claimed invention and in fact teaches away from the instantly claimed invention. The present claims, by both their product and their process recitations, patentably distinguish over Quelle, and are patentable over Quelle, either alone or in any fair combination.

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Reconsideration and withdrawal of the rejections based on Quelle are respectfully requested.

² This recitation too is founded in the recitations in the previous claims, e.g., previous claims 96 and 127-131 such that any further action on the merits in this case, other than a Notice of Allowance, in view of the previous claims must be non-final, because any new rejection has not been necessitated by this paper.

SUMMARY OF INTERVIEW ON DECEMBER 15, 2009

The interview was conducted by Examiner Srivastava and Examiner Gitomer. For the applicants, Thomas J. Kowalski, Esq., Ljiljana Minwalla, Ph.D., Esq., and Dr. Manon Cox attended the interview. The specification and claim amendments and distinctions over Quelle as herein discussed were discussed during the interview. The Examiners are thanked for the courtesies extended.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, and those of record, and the matters discussed during the personal interview on December 15, 2009, the application is in condition for allowance. Favorable reconsideration of the rejections of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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